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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/737,185
Filing Date: December 14, 2000
Appellant(s): BOWMAN ET AL.

Howard A. MacCord, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/05/06 appealing from the Office action mailed 01/10/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

The statement of the status of claims contained in the brief is correct.

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because it improperly summarizes the essence of the invention as claiming a diagnostic specimen system for identifying and controlling biomedical or toxicological specimens and managing information associated with the specimens. In fact none of the claims directed toward the specimen system recites the biomedical or toxicological specimen in the body of the claim. Rather the claims recite collection of vessels each having a wireless electronic tag; the tag in some embodiments carries information related to the specimen, which can be biomedical or toxicological, and information about the donor of the specimen. The claims also recite that the information in some embodiments includes definition of analytical tests performed on the specimen. None of the pending claims recites "toxicology tests look for toxic substances, including illegal drugs". Also, toxic compounds may be not illegal drugs, and not all illegal drugs are toxic. Moreover, there is no difference between the "biomedical specimen collection vessels" and "toxicology specimen collection vessels" recited in the claims, which raised the question of claims duplication.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

The copy of the appealed claims contained in the Appendix to the brief is correct.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-21 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All independent claims recite "a diagnostic specimen system comprising a population of biomedical specimen collection vessels" with the members of the population located in three different locations (a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory). According to 35 U.S.C. 101, patentable inventions are related to "any new and useful process, machine, manufacture, or composition". The collection vessels are the manufacture. However, it is not clear, which category of four listed in 35 U.S.C. 101, "a diagnostic specimen system comprising a population of biomedical specimen collection vessels, located in three different locations", belongs to. Also, "the subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. *Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.* The following are examples of language *that may raise a question as to the limiting effect of the language in a claim*: (A) statements of intended use or field of use, (B) "adapted to" or "adapted for" clauses, (C) "*wherein*" clauses, or (D) "whereby" clauses" (MPEP, Chapter 2106). It is not apparent, what particular structure of the diagnostic specimen system is recited in the claims, besides a particular structure recited for collection vessels. Location of a group of identical vessels at a specific place cannot be considered "a particular structure" of the diagnostic system. Moreover, it is not clear, what will happen to the subject matter of the claim, if a part of the system, after being located at the specific location for some time, will be on the way to a different location (e.g. disposal), or on the way from the manufacturing site. Also, it is not clear, if the diagnostic system manufactured

at the manufacturing site and still located at that site belongs to the claimed subject matter of the instant application. Furthermore, it is not clear, if the same vessels should always be present at these particular locations, or these vessels are moving from one place to another? If the vessels are moving and changing their location, then how can such system be definite? Besides that, the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.

The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after "wherein" (excluding the structural elements related to the vessels themselves) does not bear any patentable weight. Moreover, as it was indicated, all three "facilities" can be located in the same room: a bench with the vessels comprising tags being "a distribution facility", a special place for collecting samples, e.g. a restroom, being "a specimen collection facility", and a specimen testing laboratory being a lab in the same room. These definitions meet requirements for all claims except for claim 18.

Claim 18 is indefinite as to which data are stored at the vessel distribution facility.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 and 40-41** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129B1).

Petrick discloses a method and a business form attached to a collection vessel for establishing a chain of custody; the invention comprises using a population of biomedical

specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or **automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206)**. This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57). The method for recording information includes providing a population of biomedical specimen containers, which a collection custodian receives from a distribution location (see Figure 1), collecting a specimen from a donor in the specimen container at the specimen collection facility and electronically storing information about the

specimen, donor, and/or test to be performed in the specimen on the electronic memory tag (col. 3 and 4).

4. **Claims 1, 6-7, 9, 14-15, 19, 21 and 40-41** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

"A population of " biomedical specimen collection with "members" located at various locations of the specimen path is an inherent feature of the invention. As soon as the tag becomes attached to the test tube, the location where it occurs becomes "a distribution facility".

Attaching the tag with all information should occur before collection of the sample into the vessel. The expression "said labels are mounted on supports being provided to fix said labels onto said test tubes during the time of analysis" obviously refers to analysis in general. The situation, when the tubes are used for collecting samples without providing any information related to the sample and "the person under concern" (col. 1, line 68) seems improbable. The system inherently includes an electronic database accessible from the specimen collection facility for storing data entered at the collection facility. Exchanging information between the collection of vessels and a remote location inherently comprises an electronic network. Berney discloses a method for recording information about a diagnostic specimen by providing a population of biomedical specimen containers with wireless electronic memory tags, distributing these containers to a specimen collection facility, collecting samples and electronically storing information about the specimen, donor, and/or tests to be performed, as it is indicated previously. Moving the test tubes from the collection facility (a desk where the samples are taken) to the analysis site is what Barney discloses for his population of the test specimen tubes with electronic tags.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 5, 8, 13 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Petrick and Barney is provided above.

Although Petrick or Berney do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional

step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for Petrick's or Berney's test tubes, which are specifically designed for handling such information.

9. **Claims 16-17, 20 and 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Petric and Barney is provided above.

Petrick or Berney do not particularly teach encoding electronic signature in the electronic tag, although Petrick specifically indicates "tester's signature" in form 102, Fig. 3B. The signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Petrick's or Berney's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

10. **Claims 2 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

The disclosure of Barney is provided above.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be

self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

11. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

The disclosure of Barney is provided above.

Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

12. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman (US 5,135,313).

The disclosure of Barney is provided above.

Berney does not specifically disclose the vessel with a tamper-indicating seal.

Bowman discloses a chain-of-custody tamper-indicating seal for a bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

13. **Claim 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

The disclosure of Barney is provided above.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to modify Berney container (test tube) by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A

Berney in view of RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for any person of ordinary skill in the art to add a label with a barcode and provide the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container

Berney in view of RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier and the product (container) information.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for any person of ordinary skill in the art to add information on identity of suppliers as indicated by Leuenberger, because this conventional information is

always provided with the manufacture products, especially the test containers, and because the identity of the supplier and the vessel may assist in the proper handling the vessel.

14. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger the same way it is applied to claim 8 above, and further in view of Hoffman or Fukuzaki.

Berney in view RD 421048 A, Stevens and Leuenberger do not particularly teach encoding electronic signature in the electronic tag, although the signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Berney- RD 421048 A-Stevens-Leuenberger's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Response to the Applicants' Arguments

15. Applicant's arguments filed with the Appeal Brief on 09/05/06 have been fully considered but they are not persuasive.

Rejection of claims 1-21 and 40-44 under 35 U.S.C. 112, second paragraph.

The Appellants obviously misinterpret the examiner's rejection of the pending claims under 35 U.S.C. 112, second paragraph, as "not directed to statutory subject mater". The claims are not rejected under 35 U.S.C. 101 as "not being directed to the statutory subject matter". The examiner rather rejected the claims under 35 U.S.C. 112, second paragraph, as being indefinite

and unclear as *to what* the Appellants consider to be the statutory subject matter of the claims. The examiner unambiguously stated that the only statutory subject matter of the claims is a vessel (or a plurality of vessels) with an electronic tag, which belongs to the category "manufacture". Location of the vessels is not a manufacture and is not a further limitation to the structure of the vessel. It is not quite clear to the examiner, what specifically the Appellants' found "not in accordance with the law" in the examiner's rejection of the pending claims under 35 U.S.C. 112, second paragraph? If the Appellants consider "a specimen system having collection vessels in specified locations" a manufacture, as they state on page 14 of their arguments, the examiner cannot agree with this. The only manufacture in this recitation is the vessels themselves. Their location is totally irrelevant to the statutory subject matter indicated in 35 U.S.C. 101. It is not apparent, as to which "reasoned explanation" of this statement the Appellants expect to obtain from the examiner? Since the location of the vessels recited after "wherein" does not further limit their structure of the vessels, it does not bear any patentable weight in the claim recitation.

Appellants' referring to a frequent recitation of elements in various positions is completely irrelevant to the subject matter of the instant claims. The pending claims do not recite a unified manufacture product comprising interconnected elements, but rather a plurality of identical vessels, which are independent from each other and which can be located anywhere.

The examiner is not quite sure, which caselaw the examiner is supposed to recite in order to issue an Office action according to MPEP, specifically Chapter 2106, which recites: "the subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim: (A) statements of intended use or field of use, (B) "adapted to" or "adapted for" clauses, (C) "wherein" clauses, or (D) "whereby" clauses"?

Regarding indefiniteness of claim 18, the examiner assumes that if there is a question as to what specifically the examiner needs to search in order the examine claim 18, since the claim

recites "electronically storing data" as one of the elements without indicating, which data these might be, the examiner has a legal right to ask the Appellants, as to which data they mean in the claim. If it is unapparent, as to which data the Appellants recite in the claim, which prevents the examiner from the proper search, it is a clear case of unclarity and indefiniteness of the claim.

Rejection of claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 and 40-41 under 102(e) as being anticipated by Petrick's US 6,535,129.

As the examiner indicated in the previous Office actions, she considers instant invention and Petrick's invention disclosed in US 6,535,129 patentably indistinct. The instant invention claims a collection of vessels with wireless electronic memory tags. Petrick claims a business form comprising a wireless electronic device (tag), which is directly adhered to the specimen *or to a container containing a specimen* (claim 7). It is a clear anticipatory recitation for claim 1 of the pending application. Location of the vessels is not a patentable subject matter and does not bear any patentable weight, as was indicated previously. "A container" recited by Petrick is obviously "a plurality of containers", with singular and plural forms conventionally inter-changeable in claims recitation. Therefore, the Appellants' claim is not novel in view of the Petrick's claimed invention.

Petrick claims a business form with the wireless identification device directly adhered to the specimen container, and the Appellants recite vessels with separate wireless tags and labels with identification bar code attached to vessels (see e.g. claims 3, 12, etc.). However, having the tags and labels both on the same "business form" would have been an absolutely obvious modification, especially since two-part forms for biological specimen containers with one of them carrying a bar-code, are notoriously well known in the art. Therefore, Petrick's invention would be an obvious modification of Appellants' invention. Attachment of the wireless tag to the form (paper) inherently provides a visual indication of "de-associating" the tag from the form, when it occurs. Petrick in claim 7 recites attaching a wireless identification device directly to a specimen "*or a container containing the specimen*", with the second part of the recitation, which the Appellants for some reason forgot to mention.

Regarding the method claims: in claim 8 Petrick recites establishing "chain of custody" using the wireless tag attached to the form and container, with the "chain of custody" for a biological specimen inherently comprising distributing, transferring and analyzing specimen in

the containers. The chain of custody comprises all these elements by definition. Therefore, the recitation of claim 8 of Petrick's patent and claim 18 of the instant application are not patentably distinct.

This establishes two-way anticipatory and/or obviousness of the instant invention and Petrick's prior art, which makes them patentably indistinct.

This, in turn makes the Declaration 1.131 improper in the present case, since according to MPEP § 1.131: "Prior invention may not be established under this section if ... the rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 41.203(a) of this title, in which case an applicant may suggest interference pursuant to § 41.202(a) of this title".

Regarding different classification of the instant application and Petrick's patent, as the examiner indicated in the previous Office actions, "the Applicants' statement that just a mere classification of inventions in different classes unambiguously indicates that they are patentably distinct, is not quite correct, which is confirmed by the Applicants' own application. While it contains two separate groups of claims directed to a specimen system and a method for recording information, classified in different classes, they are not patentably distinct, and therefore were not restricted". Classification of the inventions in different classes is never a basis for restriction requirements, contrary to the Appellants' statement. It is only a patentable distinction between different inventions, which makes the proper basis for the restriction requirements.

Regarding Illuminated Examiner's Errors, the examiner would like to make several comments in this respect, as the Illuminated Errors occupy the whole chapter in the Appellants' arguments.

Referring to the first paragraph of this chapter, the examiner is not quite sure, what the Appellants are trying to state by totally misrepresenting the examiner's comments? The full recitation of the Applicants' arguments, to which the examiner raised a question of their clarity, was the following: "*If Applicant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the parties are not claiming the same patentable invention*". If the Appellants could explain, what they meant by this statement, the examiner would very much appreciate this. The examiner just said that it was not clear, as to

when the Applicants consider the inventions to be the same, since in both cases, "if Applicant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions", and even when "not" they still "are not claiming the same patentable invention". So, the examiner just wondered, in which case the Applicants considered the inventions to be patentably indistinct. That is all. The examiner did not admit that "it appears that there is no case when the Applicants' and Petrick's invention can be the same". She just indicated that this what could be concluded from the Applicants' statement. It does not mean that she agreed with this statement. Therefore, all Appellants' argumentation related to this "Examiner's observation" does not seem to be relevant to what the examiner tried to indicate.

Regarding "patentably distinct" recitation of a location of a plurality of vessels, the examiner wonders, if the Appellants would consider a recitation of a population of e.g. three identical mass spectrometers located in e.g. US, Brazil and France patentably distinct from the same mass spectrometer located in England? The examiner is not quite convinced by the Appellants' explanation of a patentable distinction of a group of identical vessels located at several locations relative to a similar vessel, location of which is not recited.

Regarding "importing limitations from the specification into the claims", the examiner finds it quite interesting that conventionally applicants consider examiner's interpretation of the claims as being deficient when the claims are not read in light of the specification. In the instant case, it is impossible not to interpret claims in light of the specification since, e.g. such term of the claims, as "chain of custody" can be understood only when reading the specification. As for using a singular *vs.* plural form for the term "container" in Petrick's patent, the examiner cannot consider the Appellants' arguments serious, since it is absolutely obvious that Petrick's patent recites a plurality of containers with biological specimen. Regarding the business form to which the tag is attached so that its de-association is visible, the examiner finds it a notoriously obvious modification of the Appellants' invention, especially since it is much easier to attach the wireless tag to the paper glued to the vessel (container) than directly to a glass or plastic vessel.

Rejection of claims 1, 6-7, 9, 14-15, 19, 21 and 40-41 under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

The examiner does not agree with the Appellants' interpretation of Berney's disclosure. It appears that they consider the expression "during the time of analysis" as an indication that the

wireless electronic tags are attached to the glass tubes during analysis in the test laboratory. If it were the case, such embodiment would totally destroy Barney's invention, which eliminates human error in assigning the right analysis to the right samples of the right patients. The Appellants did not explain the situation, when multiple samples are collected in a plurality of vessels without bearing any information on whose samples these are, and then have wireless electronic tags attached to them in order to transmit the proper information for each sample. The Appellants did not describe, how such embodiment could be enabled. The examiner also does not agree with the Appellants' statement that only the time of analysis is important to Barney, since, first, Barney does not disclose at all any sample undergoing analysis while being in the sample tube, and therefore this is already an incorrect Appellants' assumption. Second, as it is already indicated, it is impossible to imagine that the sample is collected in a tube that does not have an electronic tag with the information related to the patient, which means that the tube has to have the tag with the information about the patient written into the label. After that the sample is taken. Which means that the test tubes with detachable electronic tags are located at distribution facility (a bench with the tubes), a specimen collection facility (a desk at which the specimen is taken) and a laboratory facility. However, location of the test tubes, or facilities, is not a patentable subject matter, as was indicated above, and therefore, it is not even required to be in Barney's disclosure.

The examiner considers the Appellants' interpretation of Barney's disclosure related to claim 19 as quite "capricious", using the Appellants' own language, which was applied for a characteristics of the examiner's Office action. It is totally unclear, where the Appellants found the following disclosure in Barney: "the labels are removed in the lab, so that the labels can be reused with another test tube after the information is transferred from the them to a centralized data bank"? Barney is concerned with storing information "allowing to establish a tracebility of the entirety of the operations performed" (col. 1, lines 19-20).

Rejection of claim 44 as being anticipatory by Barney is an obvious typo, and the examiner addresses the recitation of claim 44 in obviousness-type rejection under proper section.

The examiner withdraws rejection of claim 21 as being obvious over Barney, since it is anticipatory for Barney's disclosure: the whole idea of Barney's invention is to move (transport) vessels with collected specimen to the test site with electronic tags bearing information for the patient and proper analysis to be made.

Regarding obviousness-type rejection, the Appellants clearly attack the references individually, rather than in the combination, which is not a proper response to the obviousness-type rejection of the claims. For example, Leuenberger does not have to disclose storing product information on the electronic labels, since Petrick and Barney claim storing information related to the sample, the patient and the analysis of the sample in the wireless electronic tags, which are designed for adding information. Leuenberger discloses information for the product, which would be obvious to store in the same wireless electronic tag, that is designed specifically for writing additional information.

Regarding the plastic film label with identifying bar-code, which is disclosed by Leuenberger, it is obvious to add such label simply for marking such tube and have a back-up if, for example, electronic tag is lost and the tube can become unidentified.

The remaining Appellants' arguments related to non-obviousness-type rejections are as non-convincing. For example, the Appellant's remarks that it would not have been obvious for any person of ordinary skill in the art to use Stevens' label, because it disturbs Barney's invention of eliminating all manual entry to the form are not persuasive; first, Barney did not mention anywhere that "all" useful information should be written in the electronic tags, and, second, such label secures the identity of the vessel in the case when, e.g. the tag is lost.

As for modification of Barney's tube with the tamper-indicating seal, disclosed by Bowman, such protection is necessary even when the samples are left in the same facility, since tampering is possible not only during transferring tubes with samples between facilities, but when they are stored at the same place.

Regarding claims 8 and 17, as is well known, "reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention", see *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). The recitation of claims 8 and 17 are a combination of elements disclosed in the prior art, with a clear motivation for combining the references described in detail in the rejection of the claims.

The Appellant's arguments are not convincing and therefore the rejection is maintained as was established in the previous Office action, with the exception of correction of an obvious typo for claim 44 and withdrawing an obviousness-type rejection of claim 21, which is in fact anticipated by Barney's disclosure.

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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